

(19) World Intellectual Property Organization
International Bureau(43) International Publication Date
9 August 2001 (09.08.2001)

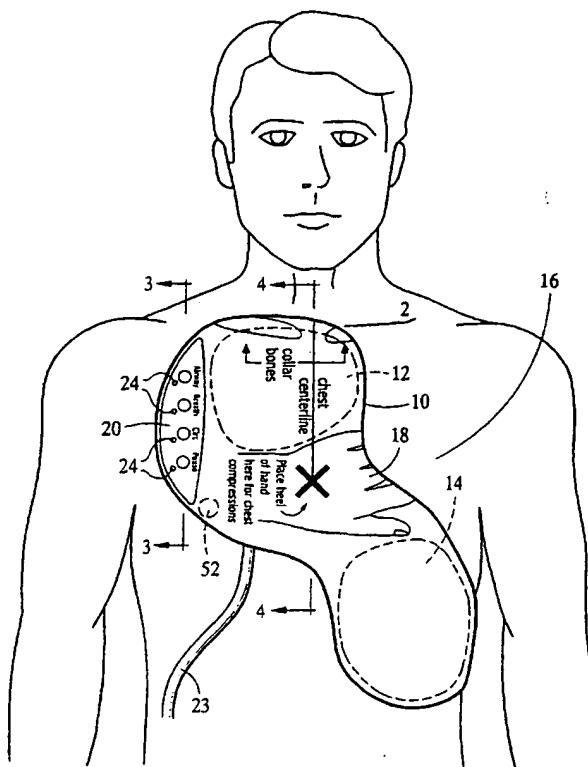
PCT

(10) International Publication Number
WO 01/56652 A1

- (51) International Patent Classification: A61N 1/365 (72) Inventor; and
(21) International Application Number: PCT/US01/03781 (75) Inventor/Applicant (for US only): FREEMAN, Gary, A. [US/US]; 47 Stearns Street, Newton Center, MA 02459 (US).
(22) International Filing Date: 5 February 2001 (05.02.2001)
(25) Filing Language: English (74) Agent: LEE, G., Roger; Fish and Richardson, P.C., 225 Franklin Street, Boston, MA 02110-2804 (US).
(26) Publication Language: English (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
(30) Priority Data: 09/498,306 4 February 2000 (04.02.2000) US (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE).
(63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application: US 09/498,306 (CIP) Filed on 4 February 2000 (04.02.2000)
(71) Applicant (for all designated States except US): ZMD CORPORATION [US/US]; 3411 Silverside Road, Wilmington, DE 19810 (US).

[Continued on next page]

(54) Title: INTEGRATED RESUSCITATION



(57) Abstract: A resuscitation system includes first (12) and second (14) high-voltage defibrillation electrodes connected to a substrate (36). A CPR pad (e.g., a semi-rigid member) (18) interconnected with the substrate (36) is configured to be located over a region of a patient's body appropriate for chest compressions when the first and second electrodes (12, 14) are positioned over regions of the patient's body appropriate for defibrillation. A compression-sensing element such as an accelerometer, or a force-sensing element, is electrically connected to a resuscitation control system. A plurality of manually operable controls (20) are mechanically interconnected with the first and second electrodes (12, 14) and the CPR pad (18) and electrically connected to the resuscitation control system (26), which provides resuscitation prompts to a rescuer based on use of the manually operable control (20) by the rescuer. A second control (30) is positioned on the resuscitation control system (26) that can be operated by a rescuer to indicate that the patient is ready for application of a defibrillation shock. A pulse detection system (52) detects whether the patient has a pulse when the substrate is in contact with the patient.

WO 01/56652 A1

BEST AVAILABLE COPY



IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

JC12 Rec'd PCT/PTC 13 APR 2005
10/531359INTEGRATED RESUSCITATION

This invention relates to integrated resuscitation systems incorporating defibrillation and cardio-pulmonary resuscitation (CPR) prompts.

Resuscitation can generally include clearing a patient's airway, assisting the patient's breathing, chest compressions, and defibrillation.

The American Heart Association's Basic Life Support for Health Care Providers textbook provides a flow chart at page 4-14 of Chapter 4 that lists the steps of airway clearing, breathing, and circulation (known as A, B, and C), for situations in which there is no defibrillator readily accessible to the rescuer.

Defibrillation (sometimes known as step D) can be performed with the use of an automatic external defibrillator (AED). Most automatic external defibrillators are actually semi-automatic external defibrillators (SAED), which require a clinician to press a start button, after which the defibrillator analyzes the patient's condition and provides a shock to the patient if the electrical rhythm is shockable and waits for user intervention before any subsequent shock. Fully automatic external defibrillators, on the other hand, do not wait for user intervention before applying subsequent shocks. As used below, automatic external defibrillators (AED) include semi-automatic external defibrillators (SAED).

Both types of defibrillators typically provide an oral stand clear warning before the application of each shock, and then the clinician is expected to stand clear of the patient and may be required to press a button indicating that the clinician is standing clear of the patient. The controls for automatic external defibrillators are typically located on a resuscitation control box.

AEDs are used typically by trained providers such as physicians, nurses, fire department personnel, and police officers. There might be one or two people at a given facility that has an AED who have been designated for defibrillation resuscitation before an ambulance service arrives. The availability of on-site AEDs along with rescuers trained to operate them is important because if the patient experiences a delay of more than 4 minutes before receiving a defibrillation shock the patient's chance of survival can drop dramatically. Many large cities and rural areas have low survival rates for defibrillation because the ambulance response time is slow, although many suburbs have higher survival rates because of the faster ambulance response time due to lack of traffic and availability of hospitals and advanced life support.

Trained lay providers are a new group of AED operators, but they rarely have opportunities to defibrillate. For example, spouses of heart attack victims may become lay providers, but these lay providers can be easily intimidated by an AED during a medical emergency. Consequently, such lay providers can be reluctant to purchase
5 AEDs, or might tend to wait for an ambulance to arrive rather than use an available AED, out of concern that the lay provider might do something wrong.

There are many different kinds of heart rhythms, some of which are considered shockable and some of them are not. For example, a normal rhythm is considered non-shockable, and there are also many abnormal non-shockable rhythms. There are also
10 some abnormal non-viable non-shockable, which means that the patient cannot remain alive with the rhythm, but yet applying shocks will not help convert the rhythm.

As an example of a non-shockable rhythm, if a patient experiences asystole, the heart will not be beating and application of shocks will be ineffective. Pacing is recommended for asystole, and there are other things that an advanced life support team
15 can do to assist such patient, such as the use of drugs. The job of the first responder is simply to keep the patient alive, through the use of CPR and possibly defibrillation, until an advanced life support team arrives. Bradycardias, during which the heart beats too slowly, are non-shockable and also possibly non-viable. If the patient is unconscious during bradycardia, it can be helpful to perform chest compressions until
20 pacing becomes available. Electro-mechanical dissociation (EMD), in which there is electrical activity in the heart but it is not making the heart muscle contract, is non-shockable and non-viable, and would require CPR as a first response. Idio-ventricular rhythms, in which the normal electrical activity occurs in the ventricles but not the atria, can also be non-shockable and non-viable (usually, abnormal electrical patterns
25 begin in the atria). Idio-ventricular rhythms typically result in slow heart rhythms of 30 or 40 beats per minute, often causing the patient to lose consciousness. The slow heart rhythm occurs because the ventricles ordinarily respond to the activity of the atria, but when the atria stop their electrical activity, a slower, backup rhythm occurs in the ventricles.

30 The primary examples of shockable rhythms, for which a first responder should perform defibrillation, include ventricular fibrillation, ventricular tachycardia, and ventricular flutter.

After using a defibrillator to apply one or more shocks to a patient who has a shockable electrical rhythm, the patient may nevertheless remain unconscious, in a shockable or non-shockable rhythm. The rescuer may then resort to chest compressions. As long as the patient remains unconscious, the rescuer can alternate
5 between use of the defibrillator (for analyzing the electrical rhythm and possibly applying a shock) and performing cardio-pulmonary resuscitation (CPR).

CPR generally involves a repeating pattern of five or fifteen chest compressions followed by a pause. CPR is generally ineffective against abnormal rhythms, but it does keep some level of blood flow going to the patient's vital organs until an advanced
10 life support team arrives. It is difficult to perform CPR over an extended period of time. Certain studies have shown that over a course of minutes, rescuers tend to perform chest compressions with less-than-sufficient strength to cause an adequate supply of blood to flow to the brain. CPR prompting devices can assist a rescuer by prompting each chest compression and breath.

15 PCT Patent Publication No. WO 99/24114, filed by Heartstream, Inc., discloses an external defibrillator having PCR and ACLS (advanced cardiac life support) prompts.

Summary of the Invention

One aspect of the invention features a combined defibrillation and CPR pad that
20 includes a substrate, a high-voltage sternum defibrillation electrode connected to the substrate, a high-voltage apex defibrillation electrode connected to the substrate, and a CPR pad (e.g., a semi-rigid member) interconnected with the substrate. The CPR pad is configured to be located over a region of a patient's body appropriate for CPR chest compressions when the sternum and apex electrodes are positioned over regions of the
25 patient's body appropriate for defibrillation. This aspect of the invention integrates CPR with defibrillation in a user-friendly manner, which, it is hoped, will lead to a high-rate of usage by lay providers, especially given that such lay providers might assume that the system might be used solely for CPR and that a resuscitation control system electrically connected to the electrodes might determine that defibrillation will
30 not be necessary.

According to another aspect of the invention, a compression-sensing element such as an accelerometer, or a force-sensing element, is interconnected with the CPR

pad, and a resuscitation control system is electrically connected to the compression-sensing element or force-sensing element and configured to receive compression or force information. This aspect of the invention allows the resuscitation control system to provide a rescuer with feedback as to compression or force applied by the rescuer
5 during CPR. It may also provide feedback as to the rate at which the rescuer performs CPR, and whether the rescuer should be performing CPR.

According to another aspect of the invention, at least one manually operatable control, such as a pause control for pausing a resuscitation procedure or a help button for requesting prompts from the resuscitation control system with respect to a particular
10 aspect of resuscitation, is mechanically connected with at least one of the sternum and apex electrodes, or with the CPR pad. The resuscitation control system is electrically connected to the manually operatable control and is configured to provide resuscitation prompts to a rescuer based on use of the manually operatable control by the rescuer. This aspect of the invention provides an arrangement that allows the rescuer to focus on
15 the patient without having to operate a resuscitation control system located away from the patient (except where direct operation of the resuscitation control system is desirable, as in connection with application of a defibrillation shock at which point the rescuer should not be near the patient).

According to another aspect of the invention, a control is positioned on the
20 resuscitation control system that can be operated by a rescuer to indicate that the patient is ready for application of a defibrillation shock, and the resuscitation control system is configured to pause at least about a second, more preferably at least about two seconds, between operation of the control by the rescuer and application of a shock to the patient. Thus, rather than apply a shock immediately that will cause the patient's body
25 to jump dramatically, the resuscitation control system maintains the rescuer safety features of a semi-automatic external defibrillator while appearing to operate more as a fully automatic external defibrillator because the time delay immediately prior to each shock leaves the rescuer with the impression that operation of the equipment is out of the hands of the rescuer. Psychologically, the rescuer may feel that if something goes
30 wrong, it might be the responsibility of the resuscitation control box rather than the rescuer. Instead of the rescuer feeling that the rescuer is controlling the resuscitation, the rescuer feels that the resuscitation control system is controlling the resuscitation and that the rescuer is simply following the instructions of the resuscitation control system.

According to another aspect of the invention, a pulse detection system, such as a system that senses light passing through a vascular bed of the patient (e.g., a pulse oximetry system) or a phonocardiogram system, is affixed to a substrate. The pulse detection system detects whether the patient has a pulse when the substrate is in contact with the patient. The control system permits or causes defibrillation shocks to be applied to the patient when the pulse detection system determines that the patient has no pulse and prevents defibrillation shocks from being applied to the patient when the pulse detection system determines that the patient has a pulse. Accordingly, this aspect of the invention provides enhanced ease of use of the defibrillation system and helps to avoid mistakes due to a rescuer's possible failure to correctly determine whether a pulse is present.

Numerous other features, objects, and advantages of the invention will be apparent from the detailed description and the drawings.

Brief Description of the Drawings

FIG. 1 is a drawing of a defibrillation electrode pad according to the invention, positioned over the chest of a patient.

FIG. 2 is a view of the front display panel of a resuscitation control box according to the invention that houses electronic circuitry and provides audible and visual prompting.

FIG. 3 is a cross-sectional drawing of the defibrillation electrode pad of FIG. 1 taken along line 3-3.

FIG. 4 is a cross-sectional drawing of the defibrillation pad of FIG. 1 taken along line 4-4.

FIG. 5 is a circuit diagram illustrating the circuit interconnections between the defibrillation electrode pad of FIG. 1 and the resuscitation control box of FIG. 2.

FIGS. 6A and 6B are a flowchart illustrating the initial routine of a resuscitation system according to the invention.

FIGS. 7A, 7B, and 7C are a flowchart illustrating the "circulation help" routine of the resuscitation system.

FIG. 8 is a flowchart illustrating the "breathing help" routine of the resuscitation system.

FIGS. 9A and 9B are a flowchart illustrating the "airway help" routine of the resuscitation system.

Detailed Description

The defibrillation and CPR assembly according to the invention combines
5 traditional AED (automatic external defibrillation) functions with CPR prompting, and thus transforms a defibrillator into a resuscitation device that combines prompts for clearing a patient's airway, breathing, chest compression, and defibrillation. Thus, the combined defibrillation and CPR assembly combines all of these aspects of resuscitation into a single protocol.

10 With reference to FIG. 1, a defibrillation electrode pad 10, which includes high-voltage apex defibrillation electrode 12 and high-voltage sternum defibrillation electrode 14, is placed on the patient's chest 16 and includes a region 18 on which a user may press to perform CPR. Legends on pad 10 indicate proper placement of the pad with respect to the patient's collarbones and the chest centerline and the proper
15 placement of the heel of the rescuer's hand.

A low-profile button panel 20 is provided on the electrode assembly. Button panel 20 has buttons 22, including buttons A (Airway Help), B (Breathing Help), C (Circulation Help) and PAUSE, and may also include adjacent light emitting diodes (LEDs) 24 that indicate which button has been most recently pressed. Button panel 20
20 is connected by a cable 23 to a remote resuscitation control box 26, shown in FIG. 2. Button panel 20 provides rigid support underneath buttons A, B, C, and PAUSE against which the switches can be pushed in order to ensure good switch closure while the electrode rests on a patient. Button panel 20 includes components that make electrical contact with silver/silver-chloride electrical circuit components screen-printed on a
25 polyester base of defibrillation electrode pad 10, as is described in detail below.

A pulse detection system based on shining light through the patient's vascular bed, e.g., a pulse oximetry system 52, is incorporated into defibrillation electrode pad 10. Pulse oximetry system 52 includes a red light-emitting diode, a near-infrared light-emitting diode, and a photodetector diode (see FIG. 5) incorporated into defibrillation
30 electrode pad 10 in a manner so as to contact the surface of the patient's chest 16. The red and near-infrared light-emitting diodes emit light at two different wavelengths, which is diffusely scattered through the patient's tissue and detected by the

photodetector diode. The information obtained from the photodetector diode can be used to determine whether the patient's blood is oxygenated, according to known noninvasive optical monitoring techniques.

In an alternative embodiment, the pulse detection system is a phonocardiogram system for listening to the sound of the victim's heart, rather than a pulse oximetry system. The phonocardiogram system includes a microphone and an amplifier incorporated within the electrode pad. Because a heart sound can be confused with microphone noise, the signal processing that must be performed by the microprocessor inside the control box will be more difficult in connection with a phonocardiogram system than in connection with a pulse oximetry system. Nevertheless, there are programs available that can enable the microprocessor to determine whether an ECG signal is present as opposed to microphone noise.

Pulse oximetry is a well-developed, established technology, but it requires good contact between the light sources and the victim's skin so that light can shine down into the victim's vascular bed. Many victims have lots of chest hair, which can interfere with good contact. It may be desirable for different types of electrode pads to be available at a given location (one having a pulse oximetry system and one having a phonocardiogram system) so that a rescuer can select an appropriate electrode pad depending on the nature of the victim.

In an alternative embodiment, instead of providing a low-profile button panel, a button housing can be provided that is affixed to an edge of the defibrillation electrode. The housing may be in the form of a clamshell formed of single molded plastic element having a hinge at an edge of the clamshell around which the plastic bends. The two halves of the clamshell can be snapped together around the electrode assembly.

The resuscitation control box (FIG. 2) includes an internal charge storage capacitor and associated circuitry including a microprocessor, an further includes off/on dial 28, and a "READY" button 30 that the rescuer presses immediately prior to application of a defibrillation shock in order to ensure that the rescuer is not in physical contact with the patient. The microprocessor may be a RISC processor such as a Hitachi SH-3, which can interface well with displays and keyboards, or more generally a processor capable of handling DSP-type (digital signal processing) operations.

The resuscitation control box has printed instructions 32 on its front face listing the basic steps A, B, and C for resuscitating a patient and giving basic instructions for

positioning the defibrillation electrode pad on the patient. A speaker 32 orally prompts the user to perform various steps, as is described in detail below.

For example, the resuscitation control box instructs the user, by audible instructions and also through a display 34 on the resuscitation control box, to check the patient's airway and perform mouth-to-mouth resuscitation, and if the patient's airway is still blocked, to press the A (Airway Help) button on the button panel (FIG. 1), upon which the resuscitation control box gives detailed prompts for clearing the patient's airway. If the patient's airway is clear and the patient has a pulse but the patient does not breathe after initial mouth-to-mouth resuscitation, the resuscitation control box instructs the user press the B (Breathing Help) button, upon which the resuscitation control box gives detailed mouth-to-mouth resuscitation prompts. If, during the detailed mouth-to-mouth resuscitation procedure, the rescuer checks the patient's pulse and discovers that the patient has no pulse, the resuscitation control box instructs the user to press the C (Circulation Help) button.

During the circulation procedure, the resuscitation control box receives electrical signals from the defibrillation electrodes and determines whether defibrillation or CPR should be performed. If the resuscitation control box determines that defibrillation is desirable, the resuscitation control box instructs the user to press the "ready" button on the resuscitation control box and to stand clear of the patient. After a short pause, the resuscitation control box causes a defibrillation pulse to be applied between the electrodes. If at any point the resuscitation control box determines, based on the electrical signals received from the electrodes, that CPR is desirable, it will instruct the user to perform CPR.

Thus, the key controls for the system are on the electrodes attached to the patient rather than the resuscitation control box. This is important because it enables the rescuer to remain focused on the patient rather than the control box. The resuscitation control box gets its information directly from the electrodes and the controls on the electrodes.

The resuscitation control box can sense electrical signals from the patient's body during pauses between CPR compressions. Also, as is described below, a compression-sensing element such as an accelerometer or a force-sensing element is provided in the region of the defibrillation electrode pad on which the user presses to perform CPR. The purpose of the compression-sensing or force-sensing element is to allow the

resuscitation control box to prompt the user to apply additional compression or force, or to prompt the user to cease CPR if the user is performing CPR at an inappropriate point in time.

Referring to FIG. 4, according to one embodiment of the invention, each
5 electrode 12, 14 (only electrode 12 is shown) of defibrillation electrode pad 10 includes a polymer-based ink containing a silver/silver-chloride suspension, which is screen-printed on a polyester or plastic base 36. The ink is used to carry the defibrillation current. The screen-printing process first involves applying a resist layer to the polyester base 36. The resist layer is basically a loose mesh of nylon or the like, in
10 which the holes have been filled in at some locations in the mesh. Then, the silver/silver-chloride ink is applied as a paste through the resist layer in a squeegee-like manner. The ink squeezes through the screen and becomes a solid layer. The ink may then be cured or dried. The silver/silver-chloride ink provides good conductivity and good monitoring capabilities.

15 Thus, the ink can be applied as pattern, as opposed to a solid sheet covering the entire polyester base. For example, U.S. Patent No. 5,330,526 describes an electrode in which the conductive portion has a scalloped or daisy shape that increases the circumference of the conductive portion and reduces burning of the patient. A conductive adhesive gel 38 covers the exposed surface of each electrode.

20 In addition, electrical circuit components are also be screen printed on the base, in the same manner as flat circuit components of membrane-covered, laminated panel controls.

Referring to FIG. 3, a rigid piece 40 of hard plastic, such as PVC or polycarbonate, is laminated beneath substrate 36 and supports buttons A, B, C, and
25 PAUSE. The rigid plastic piece 40 is glued onto substrate 36. Buttons A, B, C, and PAUSE consist of small metal dome snap-action switches that make contact between an upper conductive ink trace 42 and lower conductive ink traces 44, 46, 48, and 50. Buttons A, B, C, and PAUSE serve as controls that can be activated by the user that are physically located either on or immediately adjacent to the electrode assembly itself.
30 Each of buttons A, B, C, and PAUSE may be associated with an adjacent light-emitting diode (LED). For example, LEDs may be glued, using conductive epoxy, onto silver/silver-chloride traces on substrate 36. An embossed polyester laminate layer 54

covers conductive ink trace 42 of buttons A, B, C, and PAUSE, and a foam layer 56 is laminated beneath rigid plastic piece 40.

Referring again to FIG. 4, defibrillation electrode pad 10 includes an extension piece that is placed directly over the location on the patient's body where the rescuer performs chest compressions. This extension piece includes substrate 36, and a semi-rigid plastic supporting member 58 laminated underneath substrate 36 that covers the chest compression area. Semi-rigid supporting member 58 provides somewhat less rigidity than rigid plastic piece 409 provided at the location of buttons A, B, C, and PAUSE (illustrated in FIG. 3).

In embodiments having a force-sensing element, a polyester laminate 60, and a force-sensing resistor having two layers of carbon-plated material 62 and 64, are laminated between polyester substrate 36 and semi-rigid supporting member 58. A suitable construction of the force-sensing resistor is illustrated in the FSR Integration Guide & Evaluation Parts Catalog with Suggested Electrical Interfaces, from Interlink Electronics. The electrical contact between the two carbon-plated layers of material increases with increased pressure, and the layers of force-sensing resistive material can provide a generally linear relationship between resistance and force. Conductive ink traces 66 and 68 provide electrical connections to the two layers of the force-sensing resistor.

During chest compressions, the rescuer's hands are placed over the extension piece, and the force-sensing resistor of the extension piece is used to sense the force and the timing of the chest compressions. The force-sensing resistor provides information to the resuscitation control box so that the resuscitation control box can provide the rescuer with feedback if the rescuer is applying insufficient force. The resuscitation control box also provides coaching as to the rate at which CPR is performed. In certain situations, the resuscitation control box indicates to the rescuer that CPR should be halted because it is being performed at an inappropriate time, such as immediately prior to application of a defibrillation shock when the rescuer's hands should not be touching the patient, in which case the resuscitation control box will also indicate that the rescuer should stay clear of the patient because the patient is going to experience a defibrillation shock.

As is noted above, during CPR the rescuer pushes on the patient's chest through the extension piece in the vicinity of the electrodes. If the resuscitation control box

were to perform analysis during the chest compressions, the chest compressions would be likely to affect the sensed electrical rhythm. Instead, during the pauses between sets of compressions (for example, the pause after every fifth chest compression), the resuscitation control box can perform an electrocardiogram (ECG) analysis. The resuscitation control box might discover, for example, that the patient who is undergoing CPR is experiencing a non-shockable rhythm such as bradycardia, in which case the CPR is required in order to keep the patient alive, but then the resuscitation control box may discover that the rhythm has changed to ventricular fibrillation in the midst of CPR, in which case the resuscitation control box would instruct the rescuer to stop performing CPR so as to allow the resuscitation control box to perform more analysis and possibly apply one or more shocks to the patient. Thus, the invention integrates the rescuer into a sophisticated scheme that allows complex combinations of therapy.

In an alternative embodiment, a compression-sensing element such as an accelerometer may be used in place of a force-sensing element. The accelerometer, such as a solid-state ADXL202 accelerometer, is positioned at the location where the rescuer performs chest compressions. In this embodiment, the microprocessor obtains acceleration readings from the accelerometer at fixed time intervals such as one-millisecond intervals, and the microprocessor integrates the acceleration readings to provide a measurement of chest compression. The use of an accelerometer is based on the discovery that it is more important to measure how deeply the rescuer is compressing the chest than to measure how hard the rescuer is pressing. In fact, every victim's chest will have a different compliance, and it is important that the chest be compressed about an inch and a half to two inches in a normal sized adult regardless of the victim's chest compliance.

FIG. 5 is a circuit diagram illustrating the circuit interconnections between the defibrillation electrode pad of FIG. 1 through the cable to the resuscitation control box of FIG. 2. Sternum electrode 14 is connected to HV+ at the resuscitation control box, and apex electrode 12 is connected to HV-. A ground GND is connected to the upper conductive ink trace of buttons A, B, C, and PAUSE and to one of the layers of the force-sensing resistor. The other layer of the force-sensing resistor is connected to CPR_FORCE, and the lower conductive ink traces associated with buttons A, B, C, and PAUSE are connected to BUTTON_DETECT through resistors R1, R2, R3, and R4.

As an alternative to the use of a force-sensing resistor, a compression-sensing accelerometer 76 may be employed, in which case CPR_FORCE is replaced by CPR_ACCEL connected to accelerometer 76. Red light-emitting diode 70, near-infrared light-emitting diode 72, and photodetector diode 74 of the pulse oximetry system are connected to RLED, ILED, and ISENSE respectively, as well as ground AGND. As an alternative to the use of a pulse oximetry system, a phonocardiogram system may be employed, in which case RLED, ILED, and ISENSE is replaced by SENSE connected to microphone 78 and amplifier 80.

FIGS. 6-9 illustrate the routine of the resuscitation system described above, which is based on steps A, B, and C (airway, breathing, and circulation). Because step C includes defibrillation as well as chest compressions, all of the aspects of resuscitation are tied together in one protocol (actually, if defibrillation were considered to be a step D distinct from step C, the sequence of steps would be A, B, D, C).

The first thing the rescuer must do upon arriving at the patient is to determine whether the patient is unconscious and breathing. The rescuer opens the patient's airway, administers breaths to the patient if the patient is not breathing, and checks to determine whether a pulse is present. If there is no pulse, rather than perform chest compressions as in standard CPR, the rescuer allows the resuscitation control box to analyze the patient's electrical rhythm, and if the resuscitation control box determines that the rhythm is shockable, the resuscitation control box causes one or more shocks to be applied to the patient, and then the rescuer performs chest compressions. Thus, the invention provides a first response system that can keep the patient viable until an advanced life support time arrives to perform advanced techniques including pacing, further defibrillation, and drug therapy.

If the resuscitation control box determines that it should apply one or more defibrillation shocks to the patient, it is important that the rescuer not be anywhere near the patient when the shocks are applied to the patient. Prior to application of each shock, the resuscitation control box instructs the rescuer to please press the "ready" button when everybody is clear of the patient. The pressing of the "ready" button verifies that the rescuer's hands are off of the patient.

When the resuscitation control box detects a shockable rhythm, the resuscitation control box provides shocks of appropriate duration and energy (such as a sequence of shocks of increasing energy from 200 Joules to 300 Joules to the highest setting, 360

Joules, with the resuscitation control box performing analysis after each shock to determine whether another shock is required). If the defibrillation therapy is successful, the patient's rhythm is typically converted from ventricular fibrillation, ventricular tachycardia, or ventricular flutter to bradycardia, idio-ventricular rhythm, or asystole, all of which require CPR. It is rare to convert to a normal rhythm. Once the resuscitation control box has caused defibrillation shocks to be applied to the patient, the resuscitation control box automatically senses the patient's condition, and depending on the patient's condition will either prompt the responder to perform CPR or will not prompt the respond to perform CPR.

Defibrillation equipment can be somewhat intimidating to rescuers who are not medical professionals because the equipment can lead the rescuer to feel responsibility for having to save a loved one's life. It is important that the defibrillation equipment reduce this sense of responsibility. In particular, when the rescuer presses the "ready" button, rather than apply a shock immediately that will cause the patient's body to jump dramatically, the resuscitation control box will thank the rescuer and instruct the rescuer to remain clear of the patient and then wait for about two seconds (the resuscitation control box may describe this period to the rescuer as being an internal safety check, even if no substantial safety check is being performed). This process has an effect similar to a conversation that hands responsibility to the resuscitation control box, which makes the decision whether to apply the shock. Thus, the system maintains the rescuer safety features of a semi-automatic external defibrillator, because the rescuer must press the "ready" button before each shock, while appearing to operate more as a fully automatic external defibrillator because the time delay immediately prior to each shock leaves the rescuer with the impression that operation of the equipment is out of the hands of the rescuer. The use of CPR prompts in combination with the defibrillation also adds to the sense that the rescuer is simply following instructions from the resuscitation control box.

With reference to FIGS. 6-9, when the rescuer turns the resuscitation control box on (step 101), the resuscitation control box first informs the rescuer that the rescuer can temporarily halt prompting by pressing the PAUSE button (step 102), and then, after a pause, instructs the rescuer to check responsiveness of patient, and if the patient is non-responsive to call an emergency medical service (EMS) (steps 103, 104). The

resuscitation control box then instructs the rescuer to check the patient's airway to determine whether the patient is breathing (steps 105-107).

After a pause, the resuscitation control box then instructs the rescuer that if the patient is breathing the patient should be placed on the patient's side, unless trauma is suspected, and that the rescuer should press the PAUSE button (steps 108-109). Then the resuscitation control box instructs the rescuer to perform mouth-to-mouth resuscitation if the patient is not breathing (steps 110-114). Then the resuscitation control box instructs the rescuer to press an Airway Help button A if the patient's airway is blocked, so that the resuscitation control box can give prompts for clearing obstructed airways (steps 115 of FIG. 6B and 147-158 of FIGS. 9A-9B).

Next, after a pause (step 116a), if the resuscitation control box does not include pulse oximetry or phonocardiogram capability (step 116b), the resuscitation control box instructs the rescuer to check the patient's pulse (step 117). After another pause, the resuscitation control box instructs the rescuer to press a Breathing Help button B if the patient's pulse is okay but the patient is not breathing, so that the resuscitation control box can give prompts for assisting the patient's breathing (steps 118 and 119 of FIG. 7A and 140-146 of FIG. 8). Light-emitting diodes adjacent the various buttons indicate which button has been pressed most recently (only one light remains on at a time). The resuscitation control box next prompts the rescuer to contact an emergency medical system (step 120) and to open the patient's shirt or blouse and attach the adhesive pads (steps 122f-122h).

If the resuscitation control box does include pulse oximetry or phonocardiogram capability (step and 116b), the resuscitation control box prompts the rescuer to open the patient's shirt or blouse and attach the adhesive pads (steps 121 and 122a). If the pulse oximetry or phonocardiogram system does not provide a valid pulsatile reading (step 122b), then the flow chart proceeds to step 117. If the pulse oximetry or phonocardiogram system does provide a valid pulsatile reading and detects a pulse (steps 122b and 122c), then the resuscitation control box begins the breathing help routine (steps 122d of FIG. 7B and step 140 of FIG. 8). If the pulse oximetry or phonocardiogram system does not detect a pulse, then the resuscitation control prompts the rescuer to contact an emergency medical system (step 122e), measures the impedance of the patient to determine whether it is within an acceptable range for application of shocks (step 123) and determines whether the patient's rhythm is

shockable (steps 124). If the rhythm is shockable, the resuscitation control box causes a sequence of shocks to be applied to the patient, each shock requiring the rescuer first to press the "READY" button on the resuscitation control box (steps 124-131). After the last shock in the sequence, or if the rhythm is non-shockable, the resuscitation control box prompts the rescuer in CPR (steps 132-139). The flowchart then returns to step 117.

FIG. 8 shows the steps 140-146 for prompting the rescuer to assist the patient's breathing. After 12 breaths have been completed (step 144), the pulse oximetry or phonocardiogram system attempts to detect a pulse (step 145a), or, if the system does not include a pulse oximetry or phonocardiogram system, the resuscitation control box prompts the rescuer to check the patient's pulse. If no pulse is present, the resuscitation control box prompts the rescuer to press a Circulation Help button C (step 145b) that brings the rescuer back to the circulation portion of the flowchart. Otherwise, if a pulse is detected, then the flow chart of FIG. 8 returns to step 142.

The combined defibrillation and CPR resuscitation assembly provided by the invention can be less intimidating than conventional AEDs because the assembly is not devoted solely to defibrillation. Moreover, the resuscitation assembly is less intimidating because it accommodates common skill retention problems with respect to necessary techniques ancillary to defibrillation such as mouth-to-mouth resuscitation and CPR, including the appropriate rates of chest compression, the proper location for performing compressions, the proper manner of tilting the patient's head. In addition, because the rescuer knows that it may never even be necessary to apply a defibrillation shock during use of the resuscitation assembly, the rescuer may be more comfortable using the resuscitation assembly for mouth-to-mouth resuscitation and CPR. Unlike previous CPR prompting devices, the rescuer would be required to place the electrode assembly on top of the patient, but the rescuer would do this with the belief that the resuscitation assembly will be sensing the patient's condition and that the likelihood that the resuscitation assembly is actually going to apply a shock is low. If, during this resuscitation process, the resuscitation control box instructs the rescuer to press the "READY" button so that a defibrillation shock can be applied, the rescuer will likely feel comfortable allowing the shock to be applied to the patient. Basically, the resuscitation assembly simply tells the rescuer what to do, and by that point, given that the rescuer is already using the assembly, the rescuer is likely simply to do what the

rescuer is told to do. Essentially, the rescuer will be likely to view the resuscitation assembly as simply being a sophisticated CPR prompting device with an additional feature incorporated into it, and since rescuers are less likely to be intimidated by CPR prompting devices than AEDs, they will be likely to use the resuscitation assembly
5 according to the invention when it is needed.

Other embodiments are within the following claims. For example, in other embodiments the system can perform pacing in addition to defibrillation. Pulse detection methods other than pulse oximetry and phonocardiogram may be employed. Any method capable of detecting a victim's pulse can be used with the aspects of the
10 invention calling for pulse detection.

What is claimed is:

1. A combined defibrillation and CPR pad, comprising:
a substrate;
5 at least one first high-voltage defibrillation electrode connected to the substrate;
at least one second high-voltage defibrillation electrode connected to the
substrate; and
a CPR pad comprising a portion of the substrate or a member interconnected
with the substrate and configured to be located over a region of a patient's body
10 appropriate for CPR chest compressions when the first and second electrodes are
positioned over regions of the patient's body appropriate for defibrillation.
2. The combined defibrillation and CPR pad of claim 1, further comprising a
compression-sensing element at the location of the CPR pad.
3. The combined defibrillation and CPR pad of claim 2, wherein the
15 compression-sensing element comprises an accelerometer.
4. The combined defibrillation and CPR pad of claim 1, further comprising a
force-sensing element at the location of the CPR pad.
- X 5. The combined defibrillation and CPR pad of claim 4 wherein the force-
sensing element comprises a force-sensing resistor that comprises two layers of
20 material having a resistance therebetween that decreases with respect to increasing
force therebetween.
- X 6. The combined defibrillation and CPR pad of claim 5 wherein the two layers
of material comprise carbon.
7. The combined defibrillation and CPR pad of claim 2 further comprising a
25 resuscitation control system electrically connected to the compression-sensing element
and configured to provide a rescuer with feedback as to compression applied by the
rescuer to the CPR pad.

8. The combined defibrillation and CPR pad of claim 7 wherein the resuscitation control system is physically separate from the combined defibrillation and CPR pad.
9. The combined defibrillation and CPR pad of claim 7 wherein the resuscitation control system is configured to receive ECG signals from the electrodes for determining whether the patient is shockable.
10. The combined defibrillation and CPR pad of claim 2 further comprising a resuscitation control system electrically connected to the compression-sensing element and configured to provide a rescuer with feedback as to a rate at which the rescuer performs CPR.
11. The combined defibrillation and CPR pad of claim 2 further comprising a resuscitation control system electrically connected to the compression-sensing element and configured to provide a rescuer with feedback as to whether the rescuer should perform CPR.
12. The combined defibrillation and CPR pad of claim 11 wherein the resuscitation control system informs rescuer not to perform CPR when the system is about to cause a defibrillation shock to be applied to the patient through the first and second electrodes.
13. The combined defibrillation and CPR pad of claim 2 further comprising a resuscitation control system electrically connected to the compression-sensing element and to the electrodes and configured to perform ECG analysis during pauses between chest compressions.
14. The combined defibrillation and CPR pad of claim 11 wherein the resuscitation control system informs the user to suspend CPR while the system receives ECG signals and performs ECG analysis.
15. The combined defibrillation and CPR pad of claim 1 wherein the CPR pad is a semi-rigid member.

16. The combined defibrillation and CPR pad of claim 1 wherein the first electrode is a sternum electrode and the second electrode is an apex electrode.
17. A CPR system, comprising:
a CPR pad configured to be located over a region of a patient's body appropriate
5 for CPR chest compressions;
a compression-sensing element interconnected with the CPR pad; and
a resuscitation control system electrically connected to the compression-sensing element and configured to receive compression information from the compression-sensing element.
18. The CPR system of claim 17 wherein the compression-sensing element comprises an accelerometer.
19. The CPR system of claim 17 wherein the resuscitation control system is configured to provide a rescuer with feedback as to chest compression achieved by the rescuer during CPR.
20. The CPR system of claim 17 wherein the resuscitation control system is configured to provide a rescuer with feedback as to a rate at which the rescuer performs CPR.
21. The CPR system of claim 17 wherein the resuscitation control system is configured to provide a rescuer with feedback as to whether the rescuer should perform
20 CPR.
22. The CPR system of claim 21 wherein the resuscitation control system informs the rescuer not to perform CPR when the system is about to cause a defibrillation shock to be applied to the patient.
23. The CPR system of claim 17 wherein the resuscitation control system is
25 electrically connected to the electrodes to receive ECG signals and is configured to perform ECG analysis during pauses between chest compressions.

24. The combined defibrillation and CPR pad of claim 17 wherein the resuscitation control system informs the user to suspend CPR while the system receives ECG signals and performs ECG analysis.

25. The combined defibrillation and CPR pad of claim 17 wherein the CPR pad is a semi-rigid member.

26. The CPR system of claim 17, further comprising at least one manually operatable control mechanically connected with the CPR pad, wherein the resuscitation control system is electrically connected to the at least one manually operatable control and is configured to provide resuscitation prompts to a rescuer based on use of the manually operatable control by the rescuer.

27. A resuscitation system, comprising:
at least one first high-voltage defibrillation electrode;
at least one second high-voltage defibrillation electrode; and
at least one manually operatable control mechanically connected with and in the vicinity of at least one of the first and second electrodes; and
a resuscitation control system electrically connected to the first and second electrodes and the at least one manually operatable control and configured to provide resuscitation prompts to a rescuer based on use of the manually operatable control by the rescuer.

28. The resuscitation system of claim 27 wherein there are a plurality of manually operatable controls mechanically connected with at least one of the first and second electrodes.

29. The resuscitation system of claim 27 wherein the at least one manually operatable control comprises a pause control for pausing a resuscitation procedure.

30. The resuscitation system of claim 27 wherein the at least one manually operatable control comprises a help button for requesting prompts from the resuscitation control system with respect to a particular aspect of resuscitation.

31. The resuscitation system of claim 30 wherein the particular aspect of resuscitation comprises clearing a patient's airway.

32. The resuscitation system of claim 30 wherein the particular aspect of resuscitation comprises assisting a patient's breathing.

33. The resuscitation system of claim 30 wherein the particular aspect of resuscitation comprises assisting a patient's circulation.

5 X 34. The resuscitation system of claim 27 wherein the first electrode is a sternum electrode and the second electrode is an apex electrode.

X 35. A defibrillation system, comprising:

at least one first high-voltage defibrillation electrode;

at least one second high-voltage defibrillation electrode;

10 a control system electrically connected to the first and second electrodes and configured to cause a defibrillation shock to be applied to a patient through the first and second electrodes; and

the control system being configured to pause at least about a second between activation of the defibrillation system and application of a shock to the patient.

15 X 36. The defibrillation system of claim 35 further comprising a control positioned on the control system that can be operated by a rescuer to indicate that the patient is ready for application of a defibrillation shock, the control system being configured to pause at least about a second between operation of the control by the rescuer and application of a shock to the patient.

20 X 37. The defibrillation system of claim 35 wherein the control system is configured to pause at least about two seconds between operation of the control by the rescuer and application of the shock to the patient.

✓ 38. The defibrillation system of claim 35 wherein the control system is configured to provide resuscitation prompts to a rescuer for non-defibrillation
25 resuscitation of the patient.

X 39. The defibrillation system of claim 38 wherein the resuscitation prompts comprises CPR prompts.

X 40. The defibrillation system of claim 35 wherein the first electrode is a sternum electrode and the second electrode is an apex electrode.

41. A defibrillation system, comprising:

at least one first high-voltage defibrillation electrode;

5 at least one second high-voltage defibrillation electrode;

a control system electrically connected to the first and second electrodes and configured to cause a defibrillation shock to be applied to a patient through the first and second electrodes; and

10 a pulse detection system affixed to a substrate to which at least one of the electrodes is affixed, the pulse detection system being configured to detect whether the patient has a pulse when the substrate is in contact with the patient;

the control system being configured to permit or to cause the defibrillation shock to be applied to the patient when the pulse detection system determines that the patient has no pulse and to prevent the defibrillation shock from being applied to the
15 patient when the pulse detection system determines that the patient has a pulse.

42. The defibrillation system of claim 41 wherein the pulse detection system comprises sensing light passed through a vascular bed of the patient.

43. The defibrillation system of claim 42 wherein the pulse detection system is a pulse oximetry system.

20 44. The defibrillation system of claim 41 wherein the pulse detection system is a phonocardiogram system.

45. The defibrillation system of claim 41 wherein the control system is configured to provide resuscitation prompts to a rescuer for non-defibrillation resuscitation of the patient.

25 46. The defibrillation system of claim 45 wherein the resuscitation prompts comprises CPR prompts.

47. The defibrillation system of claim 41 wherein the first electrode is a sternum electrode and the second electrode is an apex electrode.

1/12

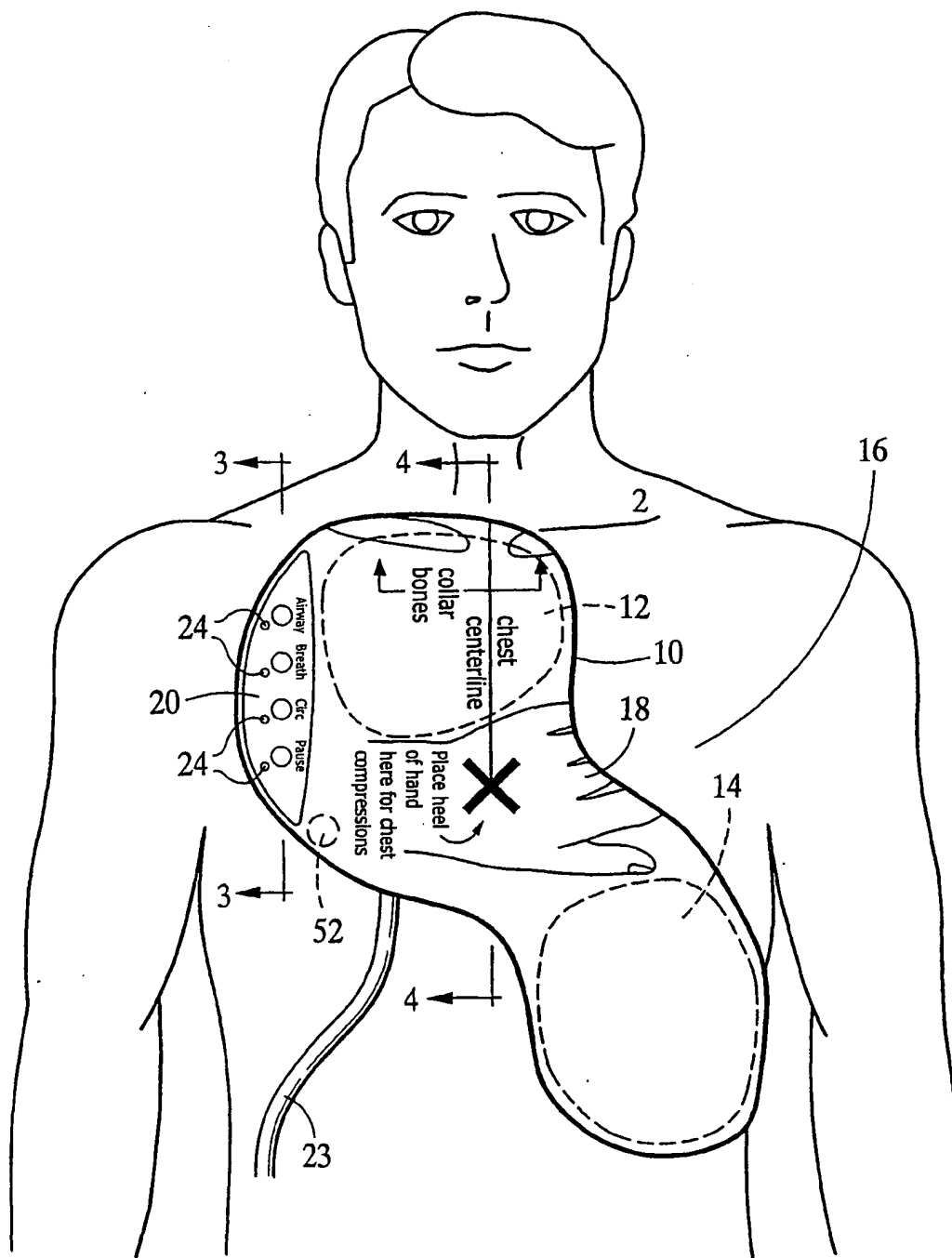


FIG. 1

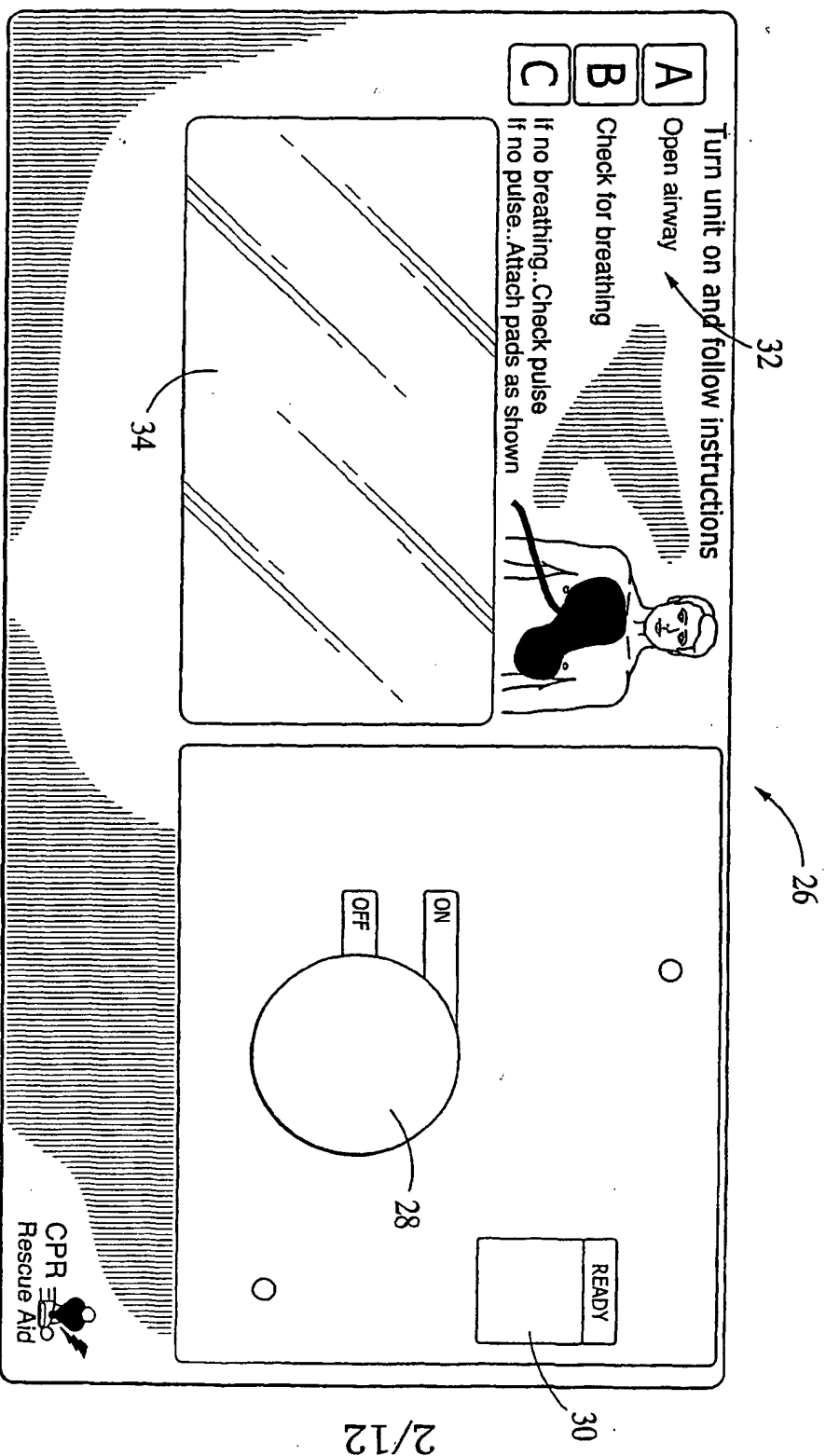


FIG. 2

3/12

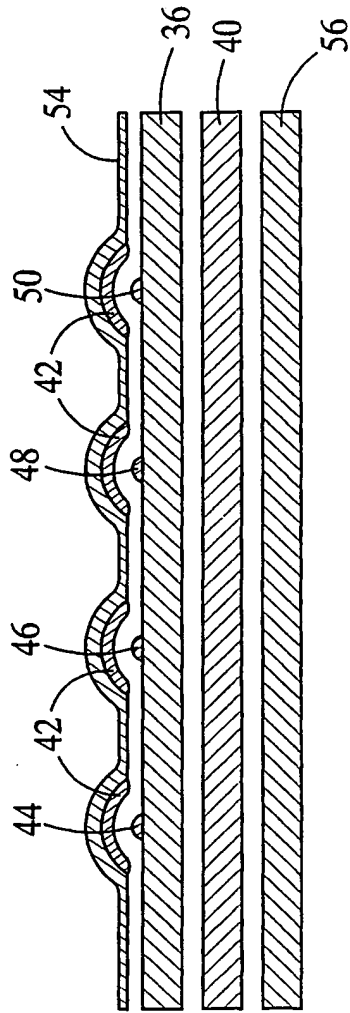


FIG. 3

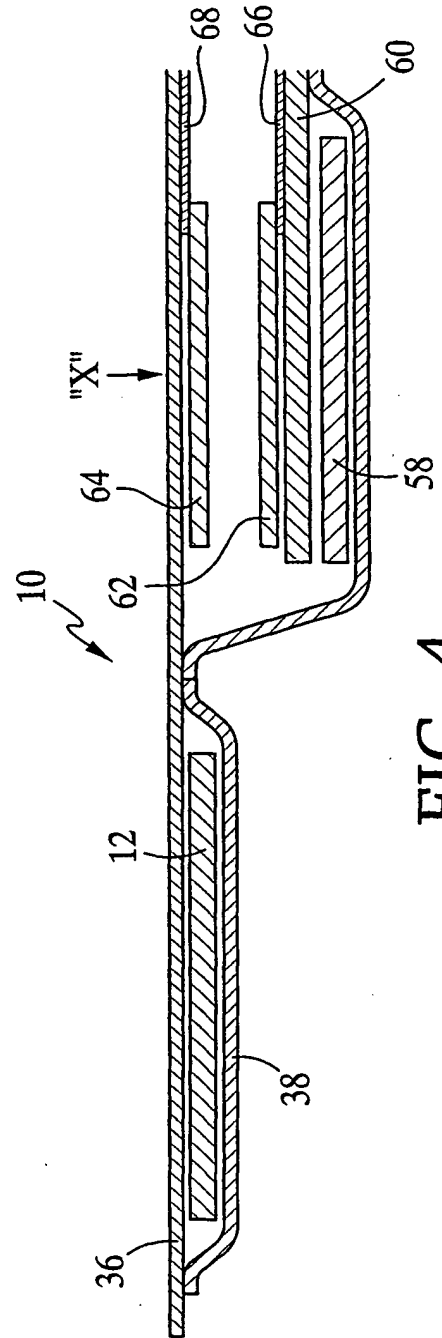


FIG. 4

4/12

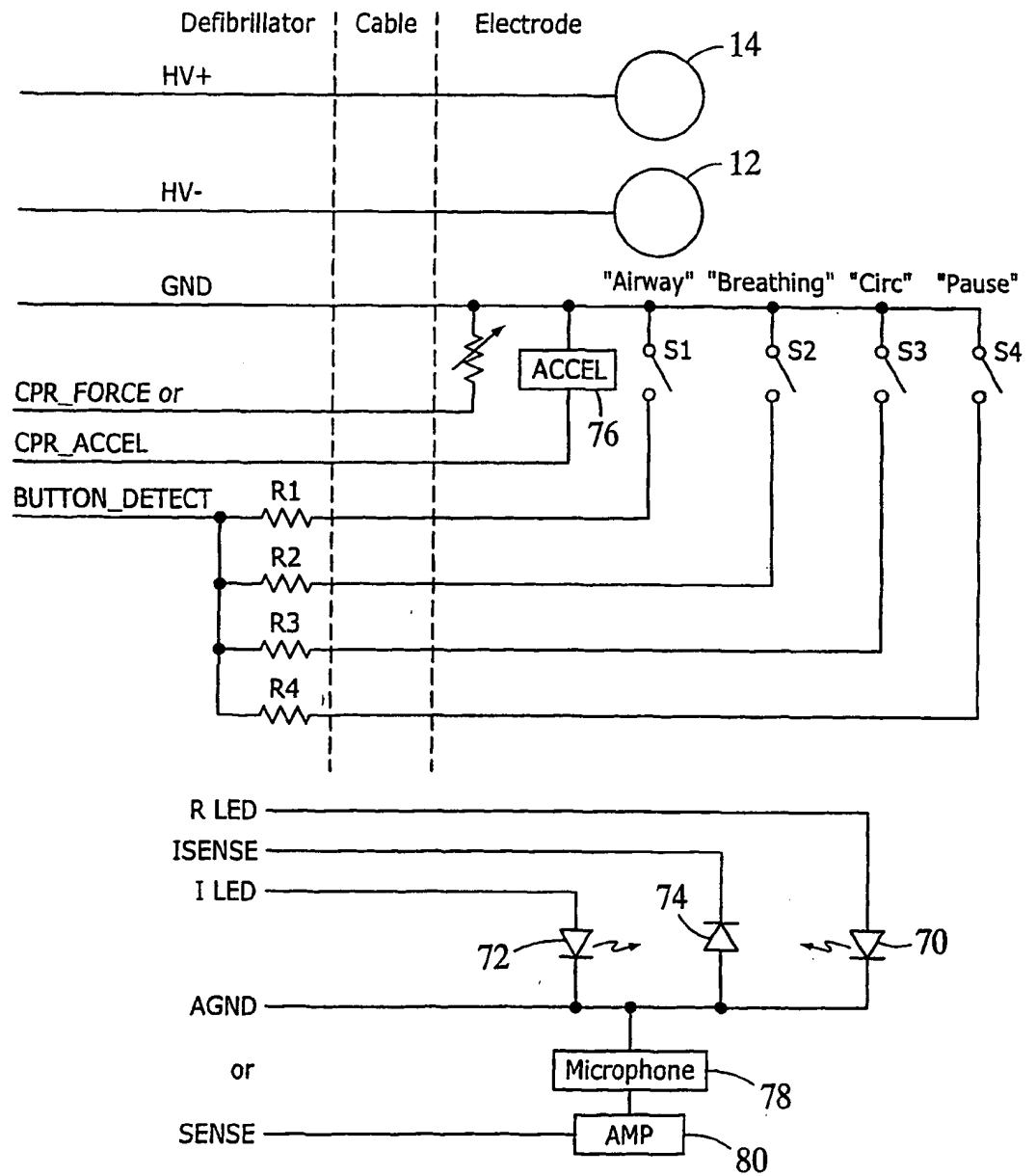
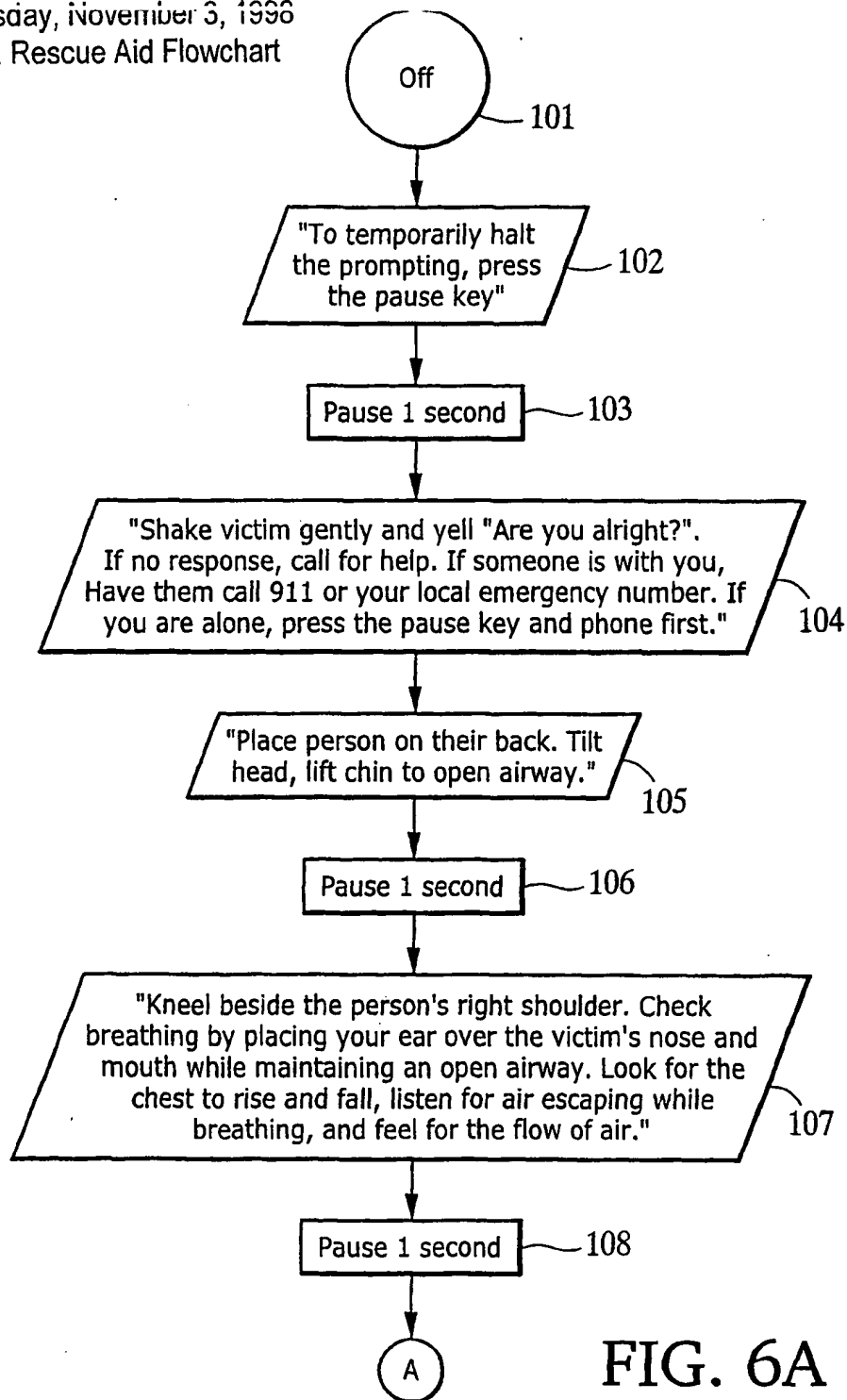


FIG. 5

5/12

Tuesday, November 3, 1998
CPR Rescue Aid Flowchart



6/12

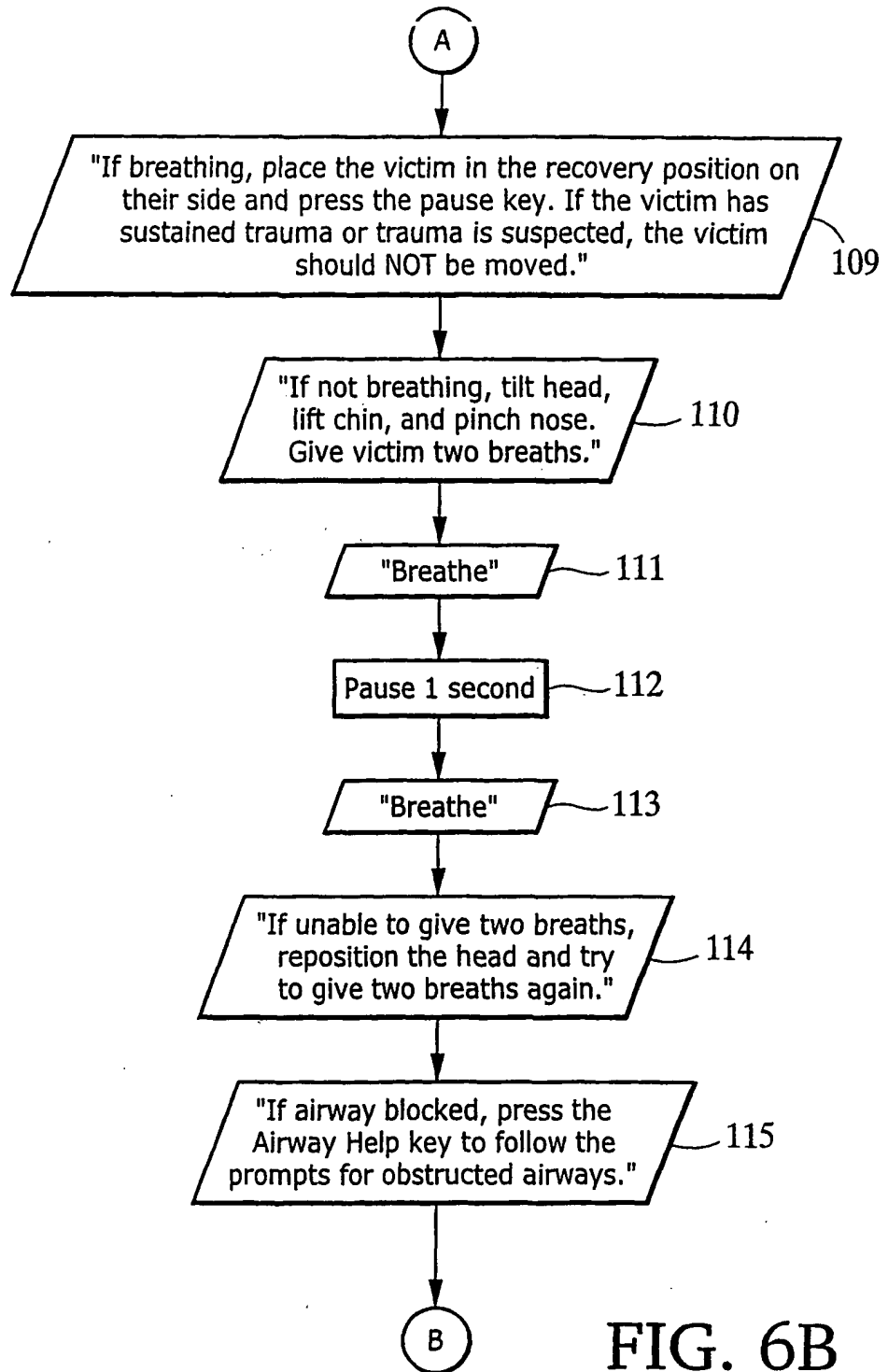


FIG. 6B

7/12

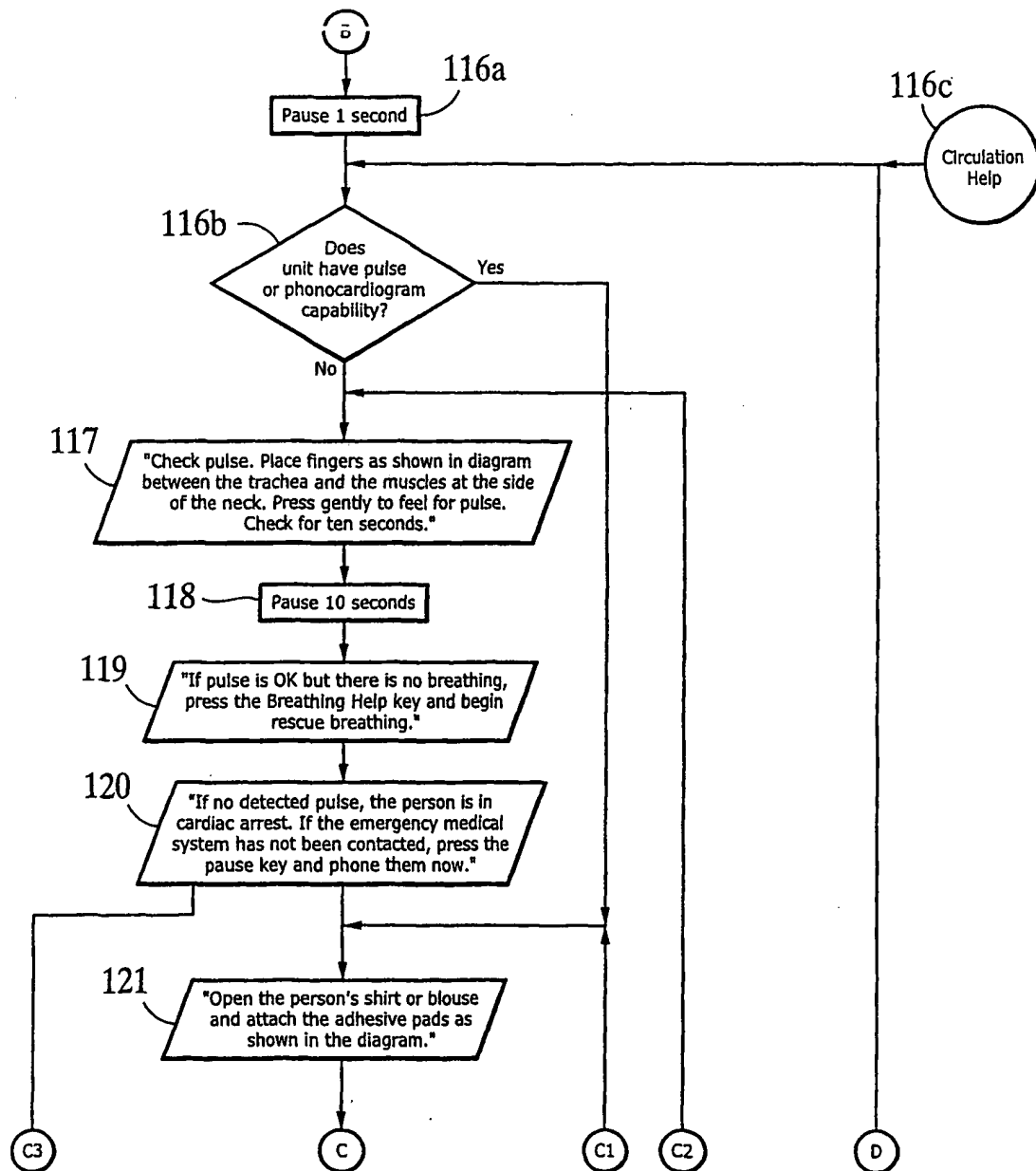


FIG. 7A

8/12

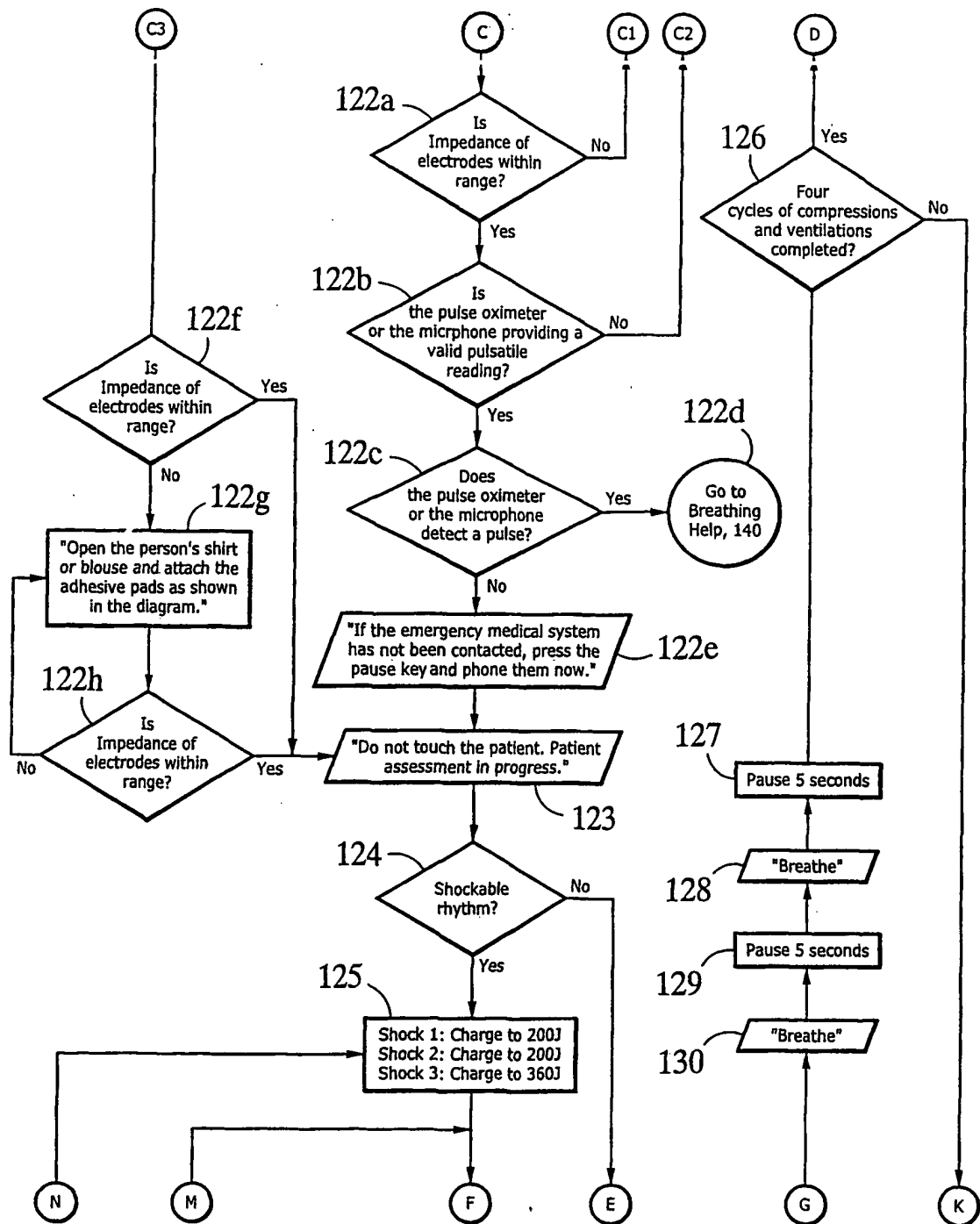


FIG. 7B

9/12

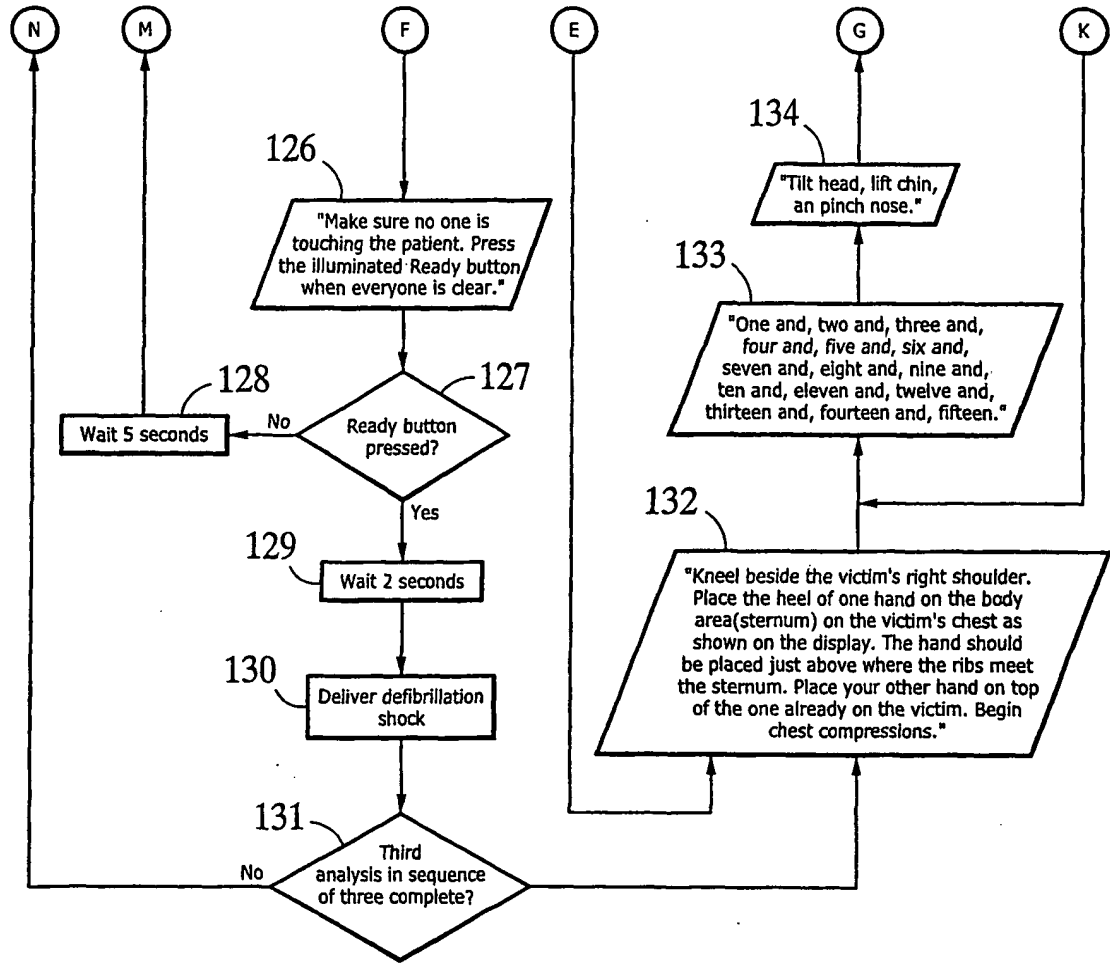


FIG. 7C

10/12

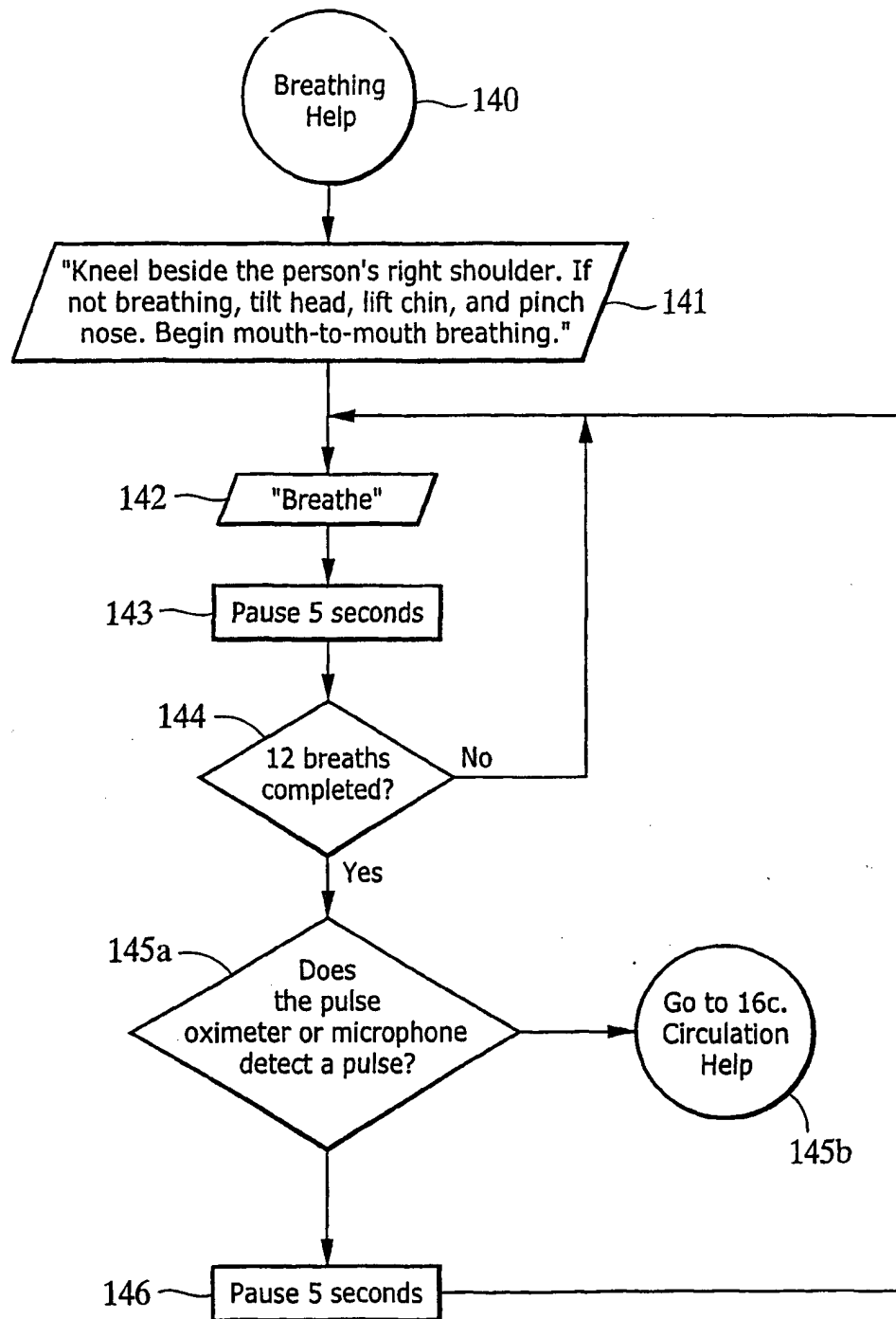


FIG. 8

11/12

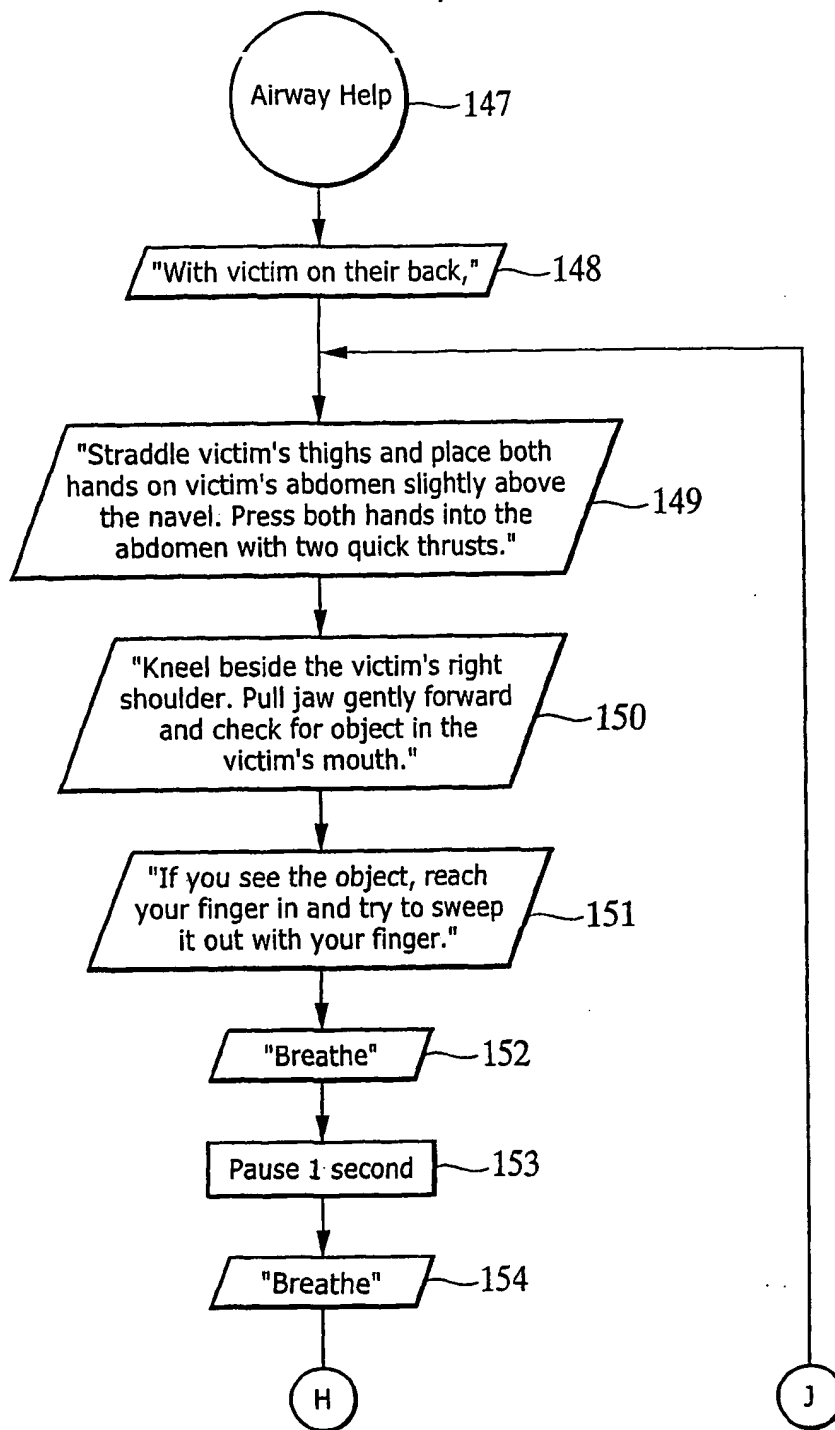


FIG. 9A

12/12

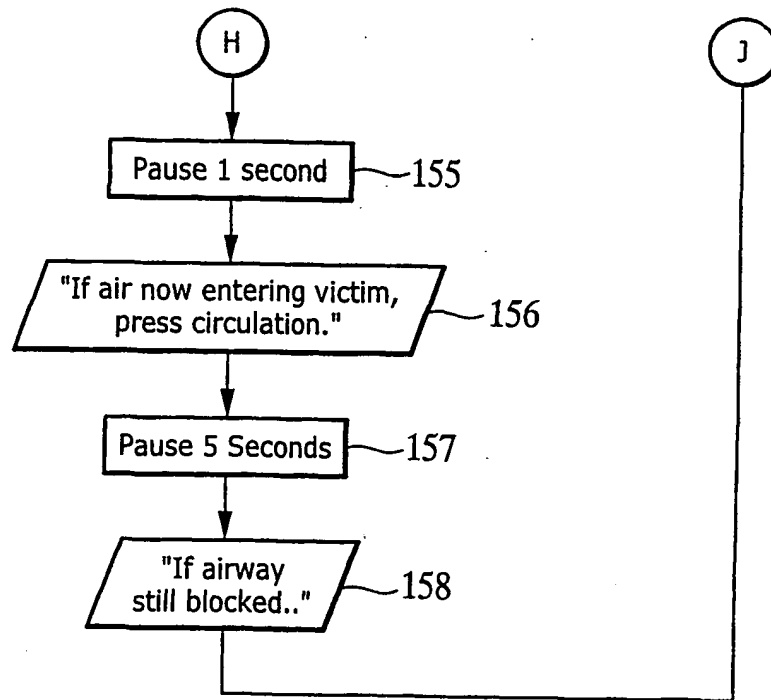
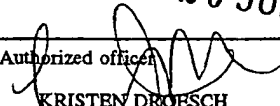


FIG. 9B

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/03781

A. CLASSIFICATION OF SUBJECT MATTER. IPC(7) : A61N 1/365 US CL : 607/6 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 601/41; 607/ 2-3, 5-8, 62, 115, 142, 152; 600/372, 382, 393, 587; 128/ 200.24, 202.13, 202.16 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P - Y,P	US 6,125,299 A (GROENKE et al) 26 Sep 2000, whole document, Figures 6-8	1-5, 7-17, 19-28,34 - 6,29-33,35-41 ,45-47
Y	US 4,610,254 A (MORGAN et al) 9 Sep 1986 col. 4, lines 44-62, Figures 3g-3h	35-41,45-47
Y	US 5,662,690 A (COLE et al) 2 Sep 1997, col. 5 line 65 - col. 6 line 5	29
Y	US 4,588,383 A (PARKER et al) 13 May 1986, whole document	30
A	US 5,466,244 A (MORGAN) 14 Nov 1995	1-47
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* Special categories of cited documents: *A* document defining the general state of the art which is not considered to be of particular relevance *E* earlier document published on or after the international filing date *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) *O* document referring to an oral disclosure, use, exhibition or other means *P* document published prior to the international filing date but later than the priority date claimed		*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art *Z* document member of the same patent family
Date of the actual completion of the international search 21 MARCH 2001		Date of mailing of the international search report 20 JUN 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer  KRISTEN DRIESCH Telephone No. (703) 605-1185

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/03781

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 6,178,357 B1 (GLINER et al) 23 Jan 2001	1-11

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

☐ BLACK BORDERS

☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES

☐ FADED TEXT OR DRAWING

☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING

☐ SKEWED/SLANTED IMAGES

☒ COLOR OR BLACK AND WHITE PHOTOGRAPHS

☐ GRAY SCALE DOCUMENTS

☐ LINES OR MARKS ON ORIGINAL DOCUMENT

☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY

☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.